**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850

***[Note: This letter was sent on April 20, 2001, to the American Hospital Association, Joint Commission on Accreditation of Healthcare Organizations, ECRI, and International Association of Healthcare Central Service Materiel Management.]***

The U.S. Food and Drug Administration is seeking volunteers from the hospital community of facilities willing to participate in a site visit program for FDA personnel. The intent is to visit hospitals that perform medical device reprocessing of class II and III single-use devices in order to develop a training course and inspectional guidance for FDA investigators. The visits are not designed for regulatory or enforcement purposes.

Of those hospitals that volunteer for participation, FDA will select possibly a half dozen facilities. Keeping in mind the strategy outlined in the enclosed enforcement document, the reprocessing activities of these facilities will be observed for instructional benefit. Again, the intent is not regulatory. We will look at the procedures followed and the records that are maintained to ascertain each hospital's "state of compliance." A special report will be provided to each hospital outlining the deficiencies identified in an effort to provide them with a better understanding of what must be done in order to comply with the applicable regulations.

The areas in which we would like the hospitals to be located include Orlando, FL; Dallas, TX; Tucson, AZ; Minneapolis, MN; Cincinnati, OH; and, the Washington D.C. area. This is due to the fact that these cities are where our investigators are located that have been identified to participate in the site visits. The deadline for volunteering is May 25. It would be helpful if the facilities interested in participating identify those devices that they reprocess at the time that they volunteer, as well as the name of the individual who will be coordinating this effort for their facility.

Once the hospital selections are made, FDA will notify the facilities and confer with the hospital coordinator at each facility in order to establish a mutually agreeable time for conducting the visit. FDA would like to schedule these site visits for June and July 2001. Any questions relative to this pilot program should be directed to Sharon Kalokerinos at (301) 594-4613 ext. 139 or SMK@cdrh.fda.gov.

Sincerely,

/s/

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and Radiological Health